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Building capacity for applied research to reduce tobacco-related harm in low- and middle-income countries: the Tobacco Control Capacity Programme (TCCP)

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Background Tobacco use is the leading cause of preventable deaths in the world. By 2030, more than 80% of these tobacco-related deaths will occur in low- and middle-income countries (LMICs). The aim of the Tobacco Control Capacity Programme (TCCP) therefore, is to reduce tobacco-related mortality and morbidity by building research capacity in LMICs.

Methods A consortium of fifteen partner organisations across eight countries (Bangladesh, Ethiopia, Ghana, India, South Africa, the Gambia, Uganda and the UK) will offer extensive research methods and leadership training opportunities to conduct high quality research projects on policy and practice and establish strong research partnerships. An example of one such study using a mixed method design to investigate tobacco industry interference in Uganda is presented.

Results The TCCP programme will produce research that can inform policies and practice within countries to prevent or reduce tobacco use. By conducting research in three key areas (tobacco taxation, reducing illicit trade, and addressing tobacco industry interference, as well as other local priorities) the programme will help to reduce tobacco disease and death and also generate revenue for governments through taxation which aids other development priorities. While conducting research in LMICs on these themes TCCP will provide evidence to support better implementation of the Framework Convention for Tobacco Controls (FCTC), which will result in reductions in tobacco-related mortality and morbidity and also help generate revenue for governments through taxation which aids other development priorities.

Conclusion The TCCP programme will create a cohort of skilled early-career researchers and research leaders who will build cohesive and successful research teams in LMICs. It will also create several collaborative networks of researchers, policy-makers and advocates to co-produce context-specific research on tobacco control and its translation into policy. This will advance implementation science in LMICs and improve population health. By generating context-specific evidence, the TCCP will support advocacy efforts to shift attitudes within communities and governments towards a stronger tobacco control. Policy makers will be assisted by the evidence generated in this programme to challenge aggressive tobacco industry tactics and implement effective tobacco control.

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Tobacco use causes more deaths globally than any other preventable risk factor, leading to approximately 7 million deaths each year (1). More than 6 million of these deaths are the result of tobacco use, with a further 890,000 from non-smokers being exposed to second-hand smoke. Given current consumption patterns and trends, global tobacco-related deaths are expected to reach more than 8 million by 2030 (2); 80% of these deaths will be in low- and middle-income countries (LMICs) (3), with half occurring in working age adults, causing significant loss to economic productivity (4). The current global deaths caused by tobacco exceeds those from HIV, tuberculosis and malaria combined (5).

Smoking causes a range of non-communicable diseases (NCDs), in addition to poor maternal health and the health harms of second-hand smoke exposure. It is the only risk factor that is linked to the four common NCD groups (i.e. cardiovascular disease, cancer, chronic lung disease and diabetes) and is also the most prevalent – causing one in every six deaths from NCDs (6). It is estimated that the global costs of smoking are equivalent to 18% of what countries around the world spend on healthcare (7). Given that there is an approximate 30-year lag at population level between the respective epidemics of tobacco use and mortality, the worst impact of the tobacco epidemic in years to come will be in LMICs. For this reason, policies to address tobacco use have been identified as ‘best-buy’ interventions for preventing NCDs in LMICs, many of which are already having near epidemics of NCDs in addition to having to fight against communicable diseases (8, 9).

Beyond this health focus, the huge social and economic impacts of tobacco production and use, and the potential to exacerbate inequalities within and between countries, are increasingly recognised across several of the 17 Sustainable Development Goals (SDGs), as part of the United Nations 2030 Agenda for Sustainable Development. In 2012 it was estimated that tobacco use would deprive the global economy of about US\$ 12.7 trillion over the following 20 years, or about 1.3% of global GDP (10). More than 40% of the global economic cost of tobacco is currently borne by LMICs (11). Tobacco control can contribute to efforts to reduce inequality within and among countries, thereby advancing SDG10.

To address these challenges a global framework for action, the Framework Convention on Tobacco Control (FCTC), was adopted by the World Health Assembly in 2003 under the auspices of the World Health Organization (WHO), and to which 181 countries are now parties (12). The treaty seeks to reduce the burden of tobacco use through key supply and demand measures laid out in its articles. Key demand measures are in WHO’s ‘MPOWER’ report including “Monitoring tobacco use and prevention policies”, “Protecting people from tobacco smoke”, “Offering help to quit tobacco use”, “Warning about the dangers of tobacco”, “Enforcing bans on tobacco advertising, promotion, and sponsorship”, and “Raising taxes on tobacco” (13). Despite widespread ratification of the FCTC, many of its articles are not yet fully implemented at the country level; where these have been ratified, enforcement is often poor. There is a significant and recognised ‘implementation gap’ in tobacco control which is exploited and exacerbated by the tobacco industry, who continue to work extensively to prevent or weaken policy development and to undermine its implementation (14).

One of the factors directly contributing to this implementation gap is the severe shortage of policy-relevant research for effective tobacco control measures in LMICs. The majority of tobacco control research happens in high income countries (HICs). This is not always transferable to LMIC settings on account of differences in the population; availability of a diverse range of tobacco products; socio-cultural determinants; related health, economic and environmental risks; associated behaviours and co-morbidities; agricultural and market economy influences; and political contexts. Even when evidence from studies in HICs should be transferrable, policymakers in LMICs may be reluctant to use or learn from these studies. To inform better policies and their implementation, research conducted in and between LMICs is needed, particularly that which involves engagement with policy makers from the outset. However, there is a dearth of researchers in these countries with the necessary substantive and methodological expertise who also have good links with relevant stakeholders (15). This is partly because the international development agenda has historically prioritised work on

communicable diseases. Despite the well documented and growing health harms caused by tobacco use in LMICs this agenda has not, until very recently, focussed on tobacco control research. Organizations such as the Bloomberg Philanthropies, Gates Foundation, International Development Research Centre, and the Fogarty International Centre have invested in tobacco control initiatives focused on promoting research, research capacity building and implementation of proven interventions in LMICs. There are also recent investments in international tobacco control research by the Global Alliance for Chronic Diseases, Medical Research Council UK, Newton Fund, Cancer Research UK (CRUK) and the National Institute for Health Research, among others. Nevertheless, development assistance for tobacco control activities in LMICs remain inadequate considering the disease burden due to tobacco use in these countries (16).

This paper presents the aims, methods and theory guiding delivery of the Tobacco Control Capacity Programme (TCCP) funded by UK Research and Innovation (UKRI) as part of the Global Challenges Research Fund.

METHODS

Aim and objectives of TCCP

The overall aim of the TCCP is to increase research capacity in seven LMICs (Bangladesh, Ethiopia, Ghana, India, South Africa, the Gambia, Uganda) to create evidence to reduce the morbidity and mortality caused by tobacco use and to advance key development priorities.

The objectives of the TCCP are to:

1. Develop a consortium of partners led by the UK Centre for Tobacco and Alcohol Studies, a UK Clinical Research Collaboration (UKCRC) Centre of Excellence involving 13 Universities.
2. Establish and train a cohort of post-doctoral fellows in the participating LMIC and UK research organisations to generate evidence to support tobacco control implementation.
3. Develop new research through a process of co-creation of research topics, data collection approaches and plans for dissemination between participating academics, government and Non-Governmental Organisations (NGOs) partners in each LMIC.
4. Apply findings from these new studies to inform the implementation of effective tobacco control and development policy measures (reducing the demand for, and supply of, tobacco products) in each participating country and internationally.
5. Engage post-doctoral fellows, co-applicants and collaborators in existing and new training opportunities in relevant research methods, tobacco control research and advocacy skills that will be offered by UK and LMIC Universities and CRUK.
6. Invest in wider stakeholder engagement (for example, Ministries of Health and Finance) to identify pathways to impact and future options for the sustainability of the programme.

Study design

Delivery of the TCCP will be guided by Cooke's framework for building research capacity that identifies six key elements: co-creation of research close to practice (objective 3); infrastructure (objective 2); skills and confidence-building (objective 5); linkages and collaborations (objectives 1 and 6); actionable dissemination (objective 4); and sustainability (objectives 6) (17).

We have used a Theory of Change approach to map these elements in an outcome framework. For the TCCP, the Theory of Change is based on the premise that by strengthening the capacity of LMIC research institutions and supporting the development of new country-specific research on tobacco control that more country relevant data will be available to support the implementation of effective tobacco control policies. This will only be realised if key stakeholders, especially those with influence over policy design and decision making, are effectively engaged throughout the programme.

To achieve this, the TCCP is being implemented by a consortium of fifteen research organisations in eight countries: Bangladesh, Ethiopia, Ghana, India, South Africa, the Gambia, Uganda and the UK. The organisations in the consortium have a diverse range of skills, expertise and experience levels of working in tobacco control research. The TCCP will tailor its approach to capacity development and research to the skills and expertise of each individual partner, via four work packages.

Work Package One – building research capacity – will contribute to addressing lack of research capacity in LMICs to undertake policy relevant research by funding 11 full-time early career research fellow positions (eight with LMIC partner research institutions and three in the UK). Each research fellow will complete a skills assessment to create an individual training programme. As well as providing practical experience of designing and conducting research, the project will support and mentor research fellows to attend training to develop their topic-specific and methodological skills and expertise.

Country specific research projects is the focus of **Work Package Two**. Working groups, made up of collaborators from the UK and LMIC research institutions as well as additional experts where appropriate, will be established to develop research proposals. A peer review process will be established to ensure quality and rigour across projects and map what is being achieved across the LMICs.

Development of country-specific projects will be guided by three research questions:

1. To what extent do national approaches to tobacco taxation align with international best practice, and how can these be enhanced to reduce tobacco consumption?
2. How can local capacity to eliminate illicit trade in tobacco products be increased, advancing implementation of the Protocol to the FCTC?
3. What are the principal barriers experienced by governments in protecting public health policy from tobacco industry interference, with specific reference to taxation and illicit trade?

These questions centre on core tobacco control issues that directly engage with broader challenges in global health and development, constitute priorities in FCTC implementation, and respond to local needs identified by our research partners and by government officials.

Research in each of the countries will address at least two of the priority areas identified above. It is envisaged that most of the research conducted in the project will generate research findings using quantitative and qualitative methods, and desk based approaches (eg, reviews of policies/ guidelines/ media stories, analysis of existing datasets).

Case study: Assessing implementation of WHO FCTC Article 5.3 and its guidelines in Uganda

Here we include a case study of one of the planned research projects in the TCCP. As noted earlier the FCTC has a number of Articles that provide guidance to governments on how to implement the FCTC. Article 5.3 is concerned with tobacco industry interference and sets out guiding principles and recommendations to protect public health policies from (and monitor the extent of) tobacco industry interference (12). However, implementation of Article 5.3 is poor, resulting in continued tobacco industry lobbying of governments which stalls, delays

or weakens tobacco control measures (1, 18). This aim of this study is to assess the extent of awareness and implementation of article 5.3 in Uganda. Ethical approval for the study has been secured from Universities in Uganda and the UK. The first stage of the study will be a desk-based review of published and unpublished literature including policy documents and parliamentary proceedings. Information related to awareness and any examples of implementation of Article 5.3 will be systematically extracted using a data extraction template and a thematic analysis conducted to summarise key findings. This will be augmented by semi-structured stakeholder interviews at the national level in Uganda (n=15), using purposive sampling, with policy makers, civil servants, advocates and non-government organisations. Interviews will be audio recorded, then transcribed verbatim and analysed using NVivo 11 (QSR International Pty Ltd, Victoria, Australia). A coding frame will be developed and, once pilot tested, transcripts will be coded to facilitate thematic analysis. Findings from the document review and the semi structure interviews will be triangulated to provide a fuller picture of awareness and implementation of Article 5.3.

Work Package Three is concerned with stakeholder engagement that will support the design of policy relevant research and generate demand for the research outputs that will be produced within the project. Stakeholder engagement events will be hosted by each LMIC research institution in years 1 and 4. These events will: provide a platform to discuss research projects; disseminate findings; highlight implications for policy; and identify future research priority areas. Investment in these activities will increase the likelihood of the project research outputs influencing policy discussions and debates.

Finally, **Work Package Four** – building collaborations and monitoring impact – has two objectives. First, to strengthen collaboration within the consortium both within and beyond the current timeframe of the project. This will be achieved through the facilitation of regular contact between TCCP team members, and annual face to face team meetings. Secondly, to monitor the progress of the programme and assess how outputs and activities may contribute to informing policy, practice and future research.

Ethics and dissemination

Research in each of the countries will be submitted for research ethics approval in the UK and the relevant LMIC before studies commence. In addition to our stakeholder engagement activities discussed under Work Package 3, we will collaborate across teams to produce peer-reviewed articles for international journals. The TCCP will also support UK and LMIC researchers to present at a range of relevant academic, practitioner and policy-relevant conferences. We will develop a TCCP programme specific and country specific websites and provide regular project updates via social media.

DISCUSSION

The TCCP programme responds to some of the key challenges to effective tobacco control and reasons for inadequate implementation of the FCTC articles in LMICs. These include a severe shortage of: academic leaders skilled in the field of tobacco control; context-specific, timely and policy-relevant research; and networks of researchers, advocates and policy makers to provide stewardship at the national level. The TCCP programme will fill this gap by building capacity among research teams in LMICs in South Asia and Sub-Saharan Africa and in the UK to conduct applied research to inform policy and practice and to provide scientific support to address the tobacco epidemic. Research capacity and impact will be created and sustained beyond the TCCP in three ways: 1) establishing a strong, supported group of post-doctoral fellows in tobacco control research; 2) establishing institutional links with academic, governmental and NGO partners, and; 3) seeking additional funding for future work, involving more countries to work across regions and NCDs.

By conducting research in LMICs on three key themes (tobacco taxation, reducing illicit trade, and addressing tobacco industry interference, as well as other local priorities) the programme

will provide data and specific examples that will help make the case for better implementation of the FCTC, resulting in reductions in tobacco disease and death and also helping to generate revenue for governments through taxation which aids other development priorities.

For early career researchers in LMIC, the TCCP programme offers a unique opportunity to develop themselves as research leaders in tobacco control. This includes a bespoke personal development programme in tobacco science and policy, mentorship, networking opportunities, and training in research and leadership. Furthermore, TCCP programme will create several collaborative networks of researchers, policymakers and advocates to co-produce context-specific research on tobacco control and its translation into policy. This will advance implementation science in LMICs and improve population health. The programme will develop capacity among LMIC researchers and advocates in applied research and in communicating research. By generating context-specific evidence, the TCCP will support advocacy efforts to shift attitudes within communities and governments towards a stronger tobacco control. Policy makers will be assisted by the evidence generated in this programme to challenge aggressive tobacco industry tactics and implement effective tobacco control.

TCCP is an ambitious programme and is likely to face several challenges. The absence or limited capacity and consequential lack of support of national bodies to coordinate tobacco control priorities, develop policy and translate evidence into action is a potential challenge that may impact the long-term sustainability of the programme. For example, lack of provision for trained LMIC research fellows to use their skills to inform local tobacco control policy and practice could result in 'brain drain' to high income countries (19, 20). The TCCP aims to build stronger links between research, policy and practice through co-creation of knowledge. Inadequate governance and research support structures (including limited regulatory and ethics review capacity and research administration and management), and material capacity (eg, peer reviewed journal availability) could also create environments that are not conducive to research. Nevertheless, the global research ethics landscape has expanded considerably since 2000, with organizations such as the Fogarty International Center, Wellcome Trust, European Developing Countries Clinical Trials Partnership, World Health Organization, UNAIDS, African AIDS Vaccine Programme, Family Health International, US Department of Health and Human Services Office for Human Research Protections [OHRP], US NIH Department of Bioethics investing in short and long-term research ethics board strengthening and training activities in LMICs (21). The TCCP offers a platform to identify where challenges exist and make recommendations for long-term, systems approaches capable of developing a critical self-sustaining mass of tobacco control research capacity in LMICs. It is also expected that the programme will be subject to pressure from the tobacco industry given their aim of further developing the markets in South Asia and Africa. At the time of writing, 1 two Freedom of Information requests have been received and responded to. While we do not know if these originate from tobacco industry actors, our previous experience with FOI requests suggests they may (22).

At this early stage in the programme delivery we have identified three key messages that may be of interest for funders, policy makers and researchers. First, it is important that funders provide ongoing opportunities to support researchers and research teams in LMICs to sustain and grow the research and networks that have been established within this and similar programmes. Second, policy makers charged with implementing the FCTC need to invest in, and be supported to build, relationships with other ministries to implement all aspects of the convention. Strong, collaborative links between authorities such as health and tax revenue bodies is needed to strengthen implementation on a country by country basis. Third, researchers, policy makers and other key stakeholders (programme managers, revenue authorities etc.) should be engaged throughout to design policy relevant research and create shared ownership, maximising potential for impact.

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